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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,811	10/23/2003	Eiji Nogami	24-009-TB	5426

23400 7590 02/07/2008
POSZ LAW GROUP, PLC
12040 SOUTH LAKES DRIVE
SUITE 101
RESTON, VA 20191

EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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02/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/690,811	Applicant(s) NOGAMI, EIJI	
	Examiner Edward J. Webman	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/30/07</u> | 6) <input type="checkbox"/> Other: _____ |

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Roreger et al.

Roreger et al teach water-swellaable gel film comprising 0.5-30% anion active water-soluble polymer, 0-75% water soluble or water-dispersible auxiliaries, and an active agent (abstract). Copolymers of methacrylic acid and methacrylic methylesters are specified (column 2 lines 50-55). Crosslinking agents such as multivalent metal cations are disclosed (column 5 lines 4-8). Thickeners, including polyvinyl alcohol, starch and cellulose derivatives, are disclosed (column 4 lines 7-13). Water dispersible auxiliaries, including a filler, such as starch and crystalline cellulose ,are disclosed (column 4 lines 61-65, column 5 lines 4-8). Multilayer films containing an active agent in layers other than the gel film are specified (column 9 lines 13-16). As to the claimed properties of taste/smell masking and ability to be swallowed, such properties must be possessed by the anticipatory composition because it is the same as that claimed. As to the claimed oral administration, such is an intended use, not considered a patentable limitation during prosecution of composition claims before the USPTO.

Applicants argue that the preamble necessarily gives meaning to the invention, and, therefore, Roreger is not on point, because it does not teach oral delivery. However, just because it does not teach such delivery does not mean the Roreger device cannot be used for applicants' claimed use. Applicants' assertion that one of ordinary skill would not be motivated to use the

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Roreger device for oral use, while perhaps relevant to a 103 rejection, is not germane to the instant 102 rejection. Applicants point to an embodiment in column 10 line 54-60 as evidence that the Roreger device will get stuck in the trachea. However, that particular embodiment recites a backing layer for that purpose. It is argued that the backing layer is optional rather than required. However, the Roreger device meets the metes and bounds of the claimed invention and, therefore, is capable of the claimed intended use and, additionally, must possess the now claimed property of release in the digestive tract.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Richter, can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


EDWARD J. WEBMAN
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